



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/908,994 | 07/17/2001 | John Shigeura | 4470 | 8729 |
| 22896 | 7590 | 10/06/2003 | EXAMINER | |
| MILA KASAN, PATENT DEPT. APPLIED BIOSYSTEMS 850 LINCOLN CENTRE DRIVE FOSTER CITY, CA 94404 | | | SISSON, BRADLEY L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1634 | |

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/908,994

Applicant(s)

SHIGEURA ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 10-14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil et al.

5. O'Neil et al., disclose a method by which nucleic acids are immobilized to an addressable solid support through nucleotide sequence-specific binding and are in turn released from their solid support in a specific manner.
6. O'Neil et al., teach the use of "recovery tags," which, as found at column 15, last paragraph, are preferably polynucleotides.
7. Column 16, bridging to column 17, discloses various forms that the solid support may take, including arrays and beads.
8. The bound nucleic acids may be sequencing ladders, as well as amplification products; see column 19.
9. Column 14 discloses separating sequencing ladders separately from the amplification product that is also bound to the solid support. Column 18, last paragraph, discloses separating the amplification product from the support while allowing for the ladder to remain attached.
10. Column 15 discloses that selective separation of amplification product or ladder can be achieved through various means, including denaturation as well as enzyme cleavage, noting that restriction enzymes and nucleases can be used.
11. The aspect of using a "flow path" (claim 10) is met by the disclosure of using capillary channels (column 4, lines 48-49).
12. In view of the disclosures of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have modified the method of O'Neil et al., such that one would have been able to have isolated one or more nucleic acids from a mixture of same whereby nucleic acids are immobilized to a solid support in an addressable manner and are released from said solid support through the altering of a physical

property (temperature). In view of the detailed disclosure, and wide applicability, the ordinary artisan would have been amply motivated and would have had a most reasonable expectation of success.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil et al. (US Patent 6,124,092) as applied to claims 10-14 and 16-20 above, and further in view of Hellyer et al. (US Patent 6,207,818 B1).

14. See above for the basis of the rejection as it pertains to the disclosure of O'Neil et al.

15. O'Neil et al., does not disclose using voltage so to alter a physical property.

16. Hellyer et al., disclose a method of effecting stringency of hybridization conditions whereby one or more nucleic acids are immobilized to a solid support such as an array through manipulation of the voltage at specific sites on the support (see columns 3-4). Accordingly, one of skill in the art can manipulate hybridization conditions through voltage on parallel with that of temperature manipulation.

17. In view of the disclosures of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of O'Neil et al., by substituting temperature modulation with voltage modulation as such allows for precise control of stringency at the various positions on an array. In view of the detailed guidance provided, the ordinary artisan would have reasonably expected to analyze and manipulate one or more samples in a simultaneous manner (see column 4 where "electronic multiplexing" is disclosed). Said ordinary artisan would have also been so motivated as "[t]he

use of electronics in this technology provides increased versatility and flexibility over such conventional methods” (column 4, second paragraph).

18. For the above reasons, and in the absence of convincing evidence to the contrary, the claims are rejected as being obvious in view of the prior art of record.

Response to argument

At page 2 of the response received 04 April 2003 applicant asserts that the prior art of record does not teach the following step:

(b) after said specific binding, releasing bound polynucleotides from a selected support by altering a physical property of that support while leaving unaltered the same physical property of at least one other of the supports,

As shown above, O'Neill et al., clearly teaches just this property. The aspect of heating (denaturing), or use of enzymatic cleavage in a selective manner whereby one set of nucleic acids is released while retaining the other, meets just such a limitation. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

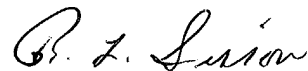
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

23. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
